

**K002615 SURGICAL SYSTEM WITH CRYOGUIDE**Nov 13, 2000  
83 days to decisionK002615 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k002615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Aug 22, 2000
Decision date	Nov 13, 2000
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endocare, Inc.</b>
Location	Irvine, CA, US
Contact	VINCENT CUTARELLI
Website	<a href="http://www.endocare.com/">http://www.endocare.com/</a>
510(k) history	22 submissions · 22 cleared · 1996-2010

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002615/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026